

REMARKS

The present invention relates in part to assay devices comprising elements for the controlled flow, delivery, incubation, separation, washing and other steps of the assay process. The devices of the present invention can provide advantageous capture efficiencies and sensitivities for the assay of a plurality of target molecules.

Following entry of the present amendments, claims 1 and 3-7 will be pending. Claims 6 and 7 have been amended to remove dependency to a cancelled claim. The amendments raise no issue of new matter and reduce issues upon appeal. Entry of the amendment is therefore appropriate.

Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

1. Obviousness-type double patenting

A. U.S. Patent No. 5,885,527

Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,885,527. Applicants provide herewith a suitable terminal disclaimer, thus mooting the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully urged.

B. U.S. Patent No. 6,019,944

Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No. 6,019,944. Applicants provide herewith a suitable terminal disclaimer, thus mooting the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully urged.

C. U.S. Patent No. 5,458,852

Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No.

5,458,852. Applicants provide herewith a suitable terminal disclaimer, thus mooting the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully urged.

D. U.S. Patent No. 6,271,040

Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,271,040. Applicants provide herewith a suitable terminal disclaimer, thus mooting the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully urged.

E. U.S. Patent No. 6,905,882

Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,905,882. Applicants provide herewith a suitable terminal disclaimer, thus mooting the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully urged.

F. U.S. Patent No. 6,767,510

Claims 1-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 and 25-37 of U.S. Patent No. 6,767,510. Applicants provide herewith a suitable terminal disclaimer, thus mooting the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully urged.

G. U.S. Patent No. 6,156,270

Claims 1-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 6,156,270. Applicants provide herewith a suitable terminal disclaimer, thus mooting the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully urged.

H. U.S. Patent Application No. 11/022,297

The provisional rejection of claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending U.S. Application No. 11/022,297 is respectfully traversed. No terminal disclaimer is procedurally

required in a case where the provisional rejection involves two pending applications and where the rejection is the sole remaining issue in the case. See MPEP 804 (I)(B) (The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.") In the event that other rejections of the present claims are successfully overcome by the current communication, the current obviousness-type double patenting rejection would then be the sole remaining rejection, and withdrawal of the instant provisional rejection would be appropriate. Applicant respectfully requests deferral of response to the instant provisional rejection until allowable subject matter has been indicated.

I. U.S. Patent Application No. 10/792,258

The provisional rejection of claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending U.S. Application No. 10/792,258 is respectfully traversed. No terminal disclaimer is procedurally required in a case where the provisional rejection involves two pending applications and where the rejection is the sole remaining issue in the case. See MPEP 804 (I)(B) (The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.") In the event that other rejections of the present claims are successfully overcome by the current communication, the current obviousness-type double patenting rejection would then be the sole remaining rejection, and withdrawal of the instant provisional rejection would be appropriate. Applicant respectfully requests deferral of response to the instant provisional rejection until allowable subject matter has been indicated.

2. 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 1-7 as allegedly failing to comply with the definiteness requirement of 35 U.S.C. § 112, second paragraph. Applicant respectfully traverses this rejection.

In addition to the indefiniteness issues addressed below, Applicants with initially address the new rejection of claim 7 for being dependent on a cancelled claim. Final Office Action, page 3, last sentence under the heading “Claim Rejections - 35 USC § 112.” This rejection, which also would appear to be applicable to claim 6, has been obviated by amendment herein for both claims.

When determining definiteness, the proper standard to be applied is “whether one skilled in the art would understand the bounds of the claim when read in the light of the specification.” *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). The settled law has established that the essential inquiry in a definiteness analysis is whether the claims, when read in light of the content of the specification and the knowledge available to the skilled artisan, set out and circumscribe the claimed subject matter with reasonable particularity. *See, e.g.*, MPEP § 2173.02; *see also, Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) (“If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.”) (emphasis added).

Moreover, as the Board of Patent Appeals and Interferences recently pointed out, even a “lack of clarity” is insufficient to establish indefiniteness:

The threshold for indefiniteness is very high: the claim must be "insolubly ambiguous". . . . If one of skill in the art would understand the scope of the claim when read in light of the specification, then the claim complies with § 112(2). Claims need not be models of clarity. As long as the meaning is discernible, then even if construction is difficult and the result equivocal, the claim is nevertheless definite. *Exxon Research & Eng'g Co.*, 265 F.3d at 1375, 60 USPQ2d at 1276; *All Dental Prodx LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80, 64 USPQ2d 1945, 1949 (Fed. Cir. 2002) (no indefiniteness despite the lack of clarity).

A. Claim 1.

The Examiner contends that claim 1 “is vague and indefinite what is intended by a ‘nonporous surface’.” Office Action, page 3. Applicant respectfully submits that the terms “porous” and “nonporous” are common English words that have well established meanings in the art. Stated simply, a porous surface is a surface comprising pores that are permeable to a

particular fluid of interest, and a nonporous surface is one that does not comprise such pores. As such, the recitation of a “nonporous surface” does not render the claim “insolubly ambiguous,” and so meets the definiteness standard of 35 U.S.C. § 112, second paragraph.

Claim 1 refers to particles comprising receptors immobilized thereon, and indicates that the “particle size range is from 1 nm to 5 μ m.” The Examiner contends that “the particle size range [in claim 1] is confusing is diameter intended [sic].” Office Action, page 3. Applicant respectfully submits that the use of such particles is common in the art, and their dimensions are typically described in terms of a “particle size,” which refers to a mean diameter for the particles used. *See, e.g.*, National Institute of Standards and Technology publication NISTR 6935, “Particle Size Measurement for Spheres with Diameters of 50 nm to 400 nm” (Exhibit 1) Particles having various “particle sizes” are available from a variety of commercial sources. *See, e.g.*, Duke Scientific Corporation Sales Bulletin 112A, “General Purpose Latex Particles” (Exhibit 2). Based on its common use in the art, that recitation of a “particle size range” does not render the claim “insolubly ambiguous,” and so meets the definiteness standard of 35 U.S.C. § 112, second paragraph.

B. Claim 6.

Claim 6 refers to a nonporous surface that “forms a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface.” The Examiner contends that it is “confusing what structure is contemplated by the claimed second surface and how it interacts with the nonporous surface. Applicant respectfully submits that, to the contrary, the claim is absolutely clear in this regard. The “second surface” is a surface other than the “nonporous surface,” and it is spaced at a capillary forming distance from the nonporous surface, thereby forming a capillary space. This description of the claimed assay device is not “insolubly ambiguous,” and so meets the definiteness standard of 35 U.S.C. § 112, second paragraph.

C. Claim 7.

Claim 7 further limits any of claims 1-5 by adding the negative limitation that “the nonporous surface is not part of a capillary space. Such devices are described in the specification as filed, for example in the section entitled “Diagnostic Elements Other Than Capillaries” The Examiner rejects this claim as being indefinite for not further limiting the claims from which claim 7 depends because it contains only a negative limitation. To the contrary, claims may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. *See, e.g., Ex Parte Kirkpatrick*, 1997 WL 33147777 (Bd. Pat. App. Interf.). In this case, the negative limitation clearly indicates that the “nonporous surface” referred to in claims 1-5 “is not part of a capillary space.” This description of the claimed assay device is not “insolubly ambiguous,” and so meets the definiteness standard of 35 U.S.C. § 112, second paragraph.

3. 35 U.S.C. §102

The Examiner has rejected claims 1-7 under 35 U.S.C. § 102(b) as allegedly being anticipated by Findlay *et al.*, U.S. Patent 5,514,550; and Wu, U.S. Patent 5,387,510. Applicant respectfully traverses this rejection.

As an initial matter, the Examiner asserts that the effective date of the preset claims should be July 11, 2000, as the various priority documents “do not contain the presently claimed ‘nonporous’ surface.” Applicant respectfully disagrees. The earliest document to which the present application claims priority is U.S. Patent 5,458,852, filed May 21, 1992. That priority document states, for example in column 2, lines 4-7, that the described devices “do not use bibulous or porous materials, such as membranes and the like as substrates for the immobilization of reagents or to control the flow of the reagents through the device.... The devices of the current invention circumvent these membrane associated problems by the use of defined surfaces, including grooved surfaces, capillarity, time gates, novel capillary means, including channels and novel fluid flow control means alone or in various combinations, all of which are constructed from non-absorbent materials.” Applicant respectfully submits that the present claims are entitled to an effective filing date of May 21, 1992.

The Examiner has cited Findlay *et al.*, U.S. Patent 5,514,550 as prior art under 35 U.S.C. § 102(b). Applicant assumes that, based on its earliest priority date of February 3, 1989, the Examiner would maintain the rejection under 35 U.S.C. § 102(e). Likewise, based on its earliest priority date of October 2, 1991, Applicant assumes that the Examiner would also maintain the rejection based on Wu, U.S. Patent 5,387,510, under 35 U.S.C. § 102(e). Applicant therefore responds to the merits of the rejection on that basis.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teaching of the specification. In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also MPEP §2131.

As amended herein, the present claims are directed to assay devices for detecting one or more target ligands comprising (i) a nonporous surface; (ii) one or more particles immobilized to the nonporous surface, where the particles have a size range from 1 nm to 5 μ m; and (iii) antibodies or fragments thereof immobilized on the particles, where the antibodies or fragments are capable of binding the target ligand(s). In contrast, both the cited patents are directed to particles having nucleic acids bound to their surfaces. Indeed, while both the Findlay *et al.* patent and the Wu patent explicitly discuss the use of antibodies, this discussion is limited to the use of antibodies only as a detectable label that may be attached to a nucleic acid that itself binds a target ligand (a nucleic acid of interest).

For example, Findlay *et al.* states at column 7, lines 15-26 (emphasis added):

The present invention also encompasses a method for using the test article described herein to detect a predetermined nucleic acid. The general description of the method is provided above. In one embodiment, the test article is used in a sandwich hybridization assay where a second probe is used to provide detection of the resulting three-part hybrid. This second probe is also complementary to the predetermined nucleic acid, and contains a moiety which provides detection in some manner (as discussed above). Preferably, the second probe is labeled with avidin, biotin, antibody, antigen, haptin, lectin, sugar (or another specific binding moiety), or other detectable moieties described below.

Similarly, Wu states at column 11, lines 45-51 (emphasis added):

In a preferred embodiment, one of the primers is labeled with a specific binding ligand such as biotin, an antibody or lectin. The labeled primer provides (through amplification) an amplified target nucleic acid which has the specific binding ligand attached. This amplified nucleic acid is detected using a detectably labeled receptor for specific binding ligand.

While both cited patents disclose immobilizing a nucleic acid on a particle for detection of a complementary nucleic acid, neither cited patent discloses, or even suggests, that particles immobilized to a nonporous surface could comprise functionally immobilized antibodies that bind to an analyte of interest.

Applicant respectfully submits that because the cited patents do not provide each and every element set forth in the claims, no *prima facie* case of obviousness has been established, and requests that the rejection be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

Respectfully submitted,

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